

## **REMARKS/ARGUMENTS**

Claims 1-31 are pending in the application. In this response, claim 1 is amended and new claims 32-34 are added. The claim amendments and new claims are all entirely supported by the application as filed. Thus, there is no issue of new matter. Claims 9, 12, 16 and 24-31 are withdrawn from consideration by the Examiner as being directed to a non-elected invention. Claims 24-31 are canceled without prejudice or disclaimer.

Upon entry of the Amendment, claims 1-23 as amended and new claims 32-34 will be pending in the application. Claims 9, 12 and 16 are withdrawn from consideration.

### **A. Interview With the Examiner**

The applicants wish to express their appreciation for the courtesies extended by the Examiner to their representatives during a telephonic interview held with the Examiner on May 21, 2008. Participating in the interview, along with the Examiner, were applicants' European Counsel, Dr. Hartmut Schwahn and Dr. Jan Wohlfhart of the Gleiss & Große firm located in Stuttgart, Germany, and Mark A. Farley, Esq. (Reg. No. 33,170) of the Ostrolenk, Faber, Gerb & Soffen, LLP firm, located in New York, NY, USA.

The claim amendments and remarks/arguments presented herein are in accordance with the matters discussed with the Examiner during the May 21<sup>st</sup> interview.

### **B. Brief Summary of the Invention**

Before discussing the substantive issues raised by the Examiner in the Office Action, applicants believe that the Examiner may find it useful to review the following non-limiting summary which attempts to set forth the 'basic concept' for which applicants' are attempting to secure patent protection in the present application.

The present invention is directed toward a transgenic sugar beet plant containing two transgenes, i.e., (a) a V-PPase and (b) a C-PPase. The invention additionally provides a process for producing such a transgenic sugar beet plant.

The transgenic beet plant according to the invention demonstrates at least one of an increased sucrose content in the beet (i.e., as compared to plants which do not have the two

transgenes indicated above), and a reduced rate of sucrose breakdown during storage of the plant material. An increase in the sucrose content of the plant is evidenced in Table 5 of Example 12 on p. 50 of the present specification.

The above-indicated effect, i.e., of an increased sucrose content in the beet and/or a reduced rate of sucrose breakdown during storage, results from a synergistic effect achieved due to the combined effect of the two transgenes, i.e., one encoding a V-PPase and the other encoding a C-PPase. Applicants have surprisingly discovered that the known increase in sugar content that is achievable due to an overexpression of C-PPase (as taught, e.g., in the Sonnewald et al. reference cited by the Examiner in the present Office Action) is synergistically increased when one utilizes, instead, a plant provided with the combination of C-PPase with V-PPase.

Applicants respectfully submit, moreover, that the present invention does not concern itself with the 'type' or 'kind' of V-PPase and/or C-PPase used to achieve the desired effect, or the manner in which the at least one sugar beet cell is transformed with these two transgenes.

### **C. Restriction Requirement**

The Office Action dated October 30, 2007 contains various grounds for restricting the claims. In response, applicants filed a response dated November 29, 2007 wherein the required elections were made, but wherein these requirements were also traversed as set forth therein.

Despite the traversal of the restriction requirements in the November 29<sup>th</sup> response, they were made FINAL by the Examiner in the present Office Action. Notwithstanding, applicants' representatives further discussed the restrictions with the Examiner during the May 21, 2008 interview. Based on these discussions, it is applicants' understanding that the Examiner indicated during the interview that he may consider the patentability of subject matter that goes beyond that which was elected in the November 29<sup>th</sup> response, provided that no further prior art search is required.

In this regard, new independent claim 34 submitted herein for consideration by the Examiner is directed to the elected subject matter (i.e., the claims of Group III and the sequences SEQ ID No. 4, SEQ ID No. 1 and SEQ ID No. 6). Moreover, it is restricted to specific *Beta*

*vulgaris* V-PPase and C-PPase transgenes with a specific promoter and being located on a single vector.

Amended claim 1, however, as well as proposed new claims 32 and 33 are somewhat broader than the scope of the claim 34. Notwithstanding, however, these claims do relate generally to the subject matter discussed in the presently cited references, namely Gaxiola (WO 02/15674); Sonnewald et al. (USP 5,492,820) and the Geigenberger et al. article (1988 Planta 205: pp. 428-437), for the reasons provided below, and thus applicants respectfully contend that no further searching is believed to be necessary for the Examiner to make a determination as to the patentability of the proposed new claims 32-33.

Each of claims 1 and 32-34 (as well as the claims which depend, directly or indirectly, from claim 1) are directed to the same aspect(s) of the invention that is briefly summarized in sub-section A above. Claims that were directed to alternate aspects, i.e., to a single transgene as in the case of claims 24-31, are deleted (without prejudice or disclaimer) from this application.

The references cited by the Examiner concern the general use of a V-PPase or a C-PPase in a plant. These references do not specifically refer to a V-PPase or a C-PPase of *Beta vulgaris*, especially with any specific gene sequence, or to any specific method of transforming a plant, especially one having two genes on one vector, having a specific promoter. The references concern the transformation of a plant with either a V-PPase of a plant, i.e., of *Arabidopsis thaliana* or with a C-PPase from a bacteria, i.e., *E. coli*. Thus, the references made of record by the Examiner are generally related to the subject matter of the invention and remain as prior art for claim 1 as presently amended, as well as for proposed new claims 32-34. Applicants thus respectfully request that amended claim 1, as well as the claims depending from that claim, be examined together with new claims 32-34.

#### D. Claim Objections

Claims 1-8, 10-11, 13-15 and 17-23 are objected to as containing non-elected subject matter. In response, claim 1 has been amended (and proposed new claims 32-34 are written) in a manner that is believed to overcome the Examiner's objection. The Examiner is, accordingly, respectfully requested to reconsider and withdraw the objections to applicants' claims.

**E. Claim Rejections Based on 35 U.S.C. §112**

Claims 1-8, 10-11, 13-15 and 17-23 are rejected under 35 U.S.C. 112, second paragraph. These rejections are respectfully traversed.

In response to the rejection, claim 1 has been amended to delete, *inter alia*, the phrase “at least one of” in sub-paragraphs (a) and (c). These amendments, which add no new matter to the application, are believed to overcome the rejection based on §-112, second paragraph, which should, therefore, be withdrawn.

**F. Claim Rejections Based on 35 U.S.C. §103**

Claims 1-8, 10-11, 13-15 and 17-23 are rejected under 35 U.S.C.103 as being allegedly unpatentable over Gaxiola (WO 02/15674) in view of Sonnewald et al. (USP 5,492,820) and further, in view of Geigenberger et al. (1998 Planta 205, pp. 428-437) for the reasons set forth on pp. 4-7 of the Office Action. These rejections are respectfully traversed, in light of the amendments to claim 1, for the reasons set forth below.

As indicated above, the present invention is directed *inter alia* to a process (as recited, e.g., in independent claim 1 as amended) for producing a transgenic sugar beet plant having (a) an increased sucrose content in the beet, or (b) a reduced rate of sucrose breakdown during storage, or (c) both (a) and (c) above. In the process which is the subject of the invention, both a vacuolar pyrophosphatase (V-PPase) and a cytosolic or a nucleus-located soluble phosphatase (C-PPase) are used as transgenes.

It has surprisingly been found by the inventors of the present invention that the co-transformation of these two transgenes results in an increased sucrose content in the beet, as measured in percent by weight (see, for example, Table 5 in Example 12 on p. 50 of the written description of the invention as contained in the specification). The sucrose content was not only increased compared to a non-transformed plant, but also as compared to plants that were transformed with only one of the two genes, i.e., with either V-PPase or C-PPase. The presently claimed method thus produces an unexpected synergistic effect compared to that achieved with the use of (only) one or the other of V-PPase or C-PPase. The unexpected synergistic effect thus should be taken as evidence of the non-obvious of applicants’ claimed invention.

Turning first to a discussion of the Gaxiola reference, applicants submit that the subject reference discloses a method of producing a transgenic plant with increased meristematic activity, wherein the method comprises transforming the plant with a vector comprising a vacuolar pyrophosphatase (AVP1) operatively linked with a promoter. The AVP1 overexpression results in plants with increased meristematic activity, increased cellular division activity and oversize vegetative and sexual structures (see Gaxiola, p. 2, first paragraph). Gaxiola et al. do not disclose a correlation, however, between the overexpression of a vacuolar pyrophosphatase (V-PPase) and the sucrose content in a plant, especially an increased sucrose content in a “sink” organ of a plant, as occurs in the present case, or a reduced rate of sucrose breakdown during storage.

On the contrary, one having an ordinary level of skill in this art at the time the present invention was made would naturally assume that a plant produced according to the teachings of Gaxiola would, instead, show a decreased sucrose content (in percentage per weight) since the weight of the plant is increased due to the increase in cellular division activity and the production of the oversized vegetative and sexual structures which require additional energy, i.e., sucrose, for their formation. If the Examiner requires it, applicants are in a position to supply evidence underlying the above argument relating to the energy-consuming effect of an increased cellular division activity.

In light of the situation as described above, therefore, one skilled in this art would not have been led toward transforming a sugar beet plant with a V-PPase with the objective of obtaining a transgenic beet plant having an increased sucrose content in the beet or a reduced rate of sucrose breakdown during storage.

The Sonnewald et al. reference combined by the Examiner with Gaxiola to reject applicants’ claims also neither teaches or suggests the invention as claimed, whether taken alone or in combination with Gaxiola. That is, Sonnewald et al. disclose a transformation of a plant, especially tobacco and potato plants, with a cytosolic pyrophosphatase. The transformed plant shows an increased accumulation of sucrose in the sources, i.e., in their leaves (see, Sonnewald et al. col. 10, line 16 to col. 11, line 3, but not in “sinks”, e.g., beets as is recited in the claims of the present application. The patentees do speculate, however (see, e.g. col. 12, the last paragraph)

that the specific expression of the *E. coli* pyrophosphatase leads to an increased supply of sink organs with sucrose, thus increasing the yield. This statement amounts to mere speculation, however, which is totally unsupported by proof using experimental data.

One having an ordinary level of skill in this art would, furthermore, not be encouraged by Geigenberger et al., by the mere speculation contained in Sonnewald et al. to transform a sugar beet plant with a C-PPase to obtain a transgenic beet plant with increased sucrose content or with a reduced rate of sucrose breakdown during storage for the reasons which are set forth below.

Uwe Sonnewald is a author of both the Sonnewald et al. patent and the Geigenberger et al. article and is, therefore, a member of the same scientific group as the other co-authors of those references. The experimental results set forth in the later (in time) “Geigenberger et al.” publication should, thus, be deemed to ‘overwrite’ (i.e., supplant) the data and hypotheses contained in the Sonnewald et al. references with the effect of rendering them void in the face of later (in time), more complete evidence as contained in the Geigenberger reference dated in 1997. In contrast, the reference which matured into the Sonnewald et al. ‘820 patent contains experimental data which is traceable back to 1990, i.e., some seven years prior to the publication of the Geigenberger reference.

Therefore, the Geigenberger et al. article is the most relevant document to rely upon in considering the validity of the speculations contained in Sonnewald, et al. In regard to this issue, Geigenberger et al. demonstrate that the overexpression of C-PPase **leads to increased sucrose degradation** in plants, especially in potato tubers (see, e.g. the title of the Geigenberger et al. reference). **This represents a clear “teaching away”, therefore, from the invention as presently claimed.** According to p. 431, the second and third paragraph, the rate of sucrose uptake was similar in the wild type and in the transformed plants. In discs taken from wild type tubers, only a small portion of the absorbed sucrose is metabolized after two hours and starch is a major product. A larger proportion of the absorbed sucrose was metabolize, and a larger portion of the metabolized label was converted to starch in discs from the transformed tubers than in those of the wild type.

At from p. 434 last paragraph to p. 435, first and second paragraphs of the subject Geigenberger reference, it is once again stated that the overexpression of C-PPase leads to a

stimulation of sucrose degradation and starch synthesis in growing potato tubers. Even if a higher sucrose amount may be found as a metabolite in the plant, as shown in Fig. 2 of Geigenberger et al., this sucrose is immediately degraded. The teaching of Geigenberger et al. thus contradicts the speculation found in the Sonnewald et al. reference and would thus serve to discourage one skilled in this art from attempting to transform a sugar beet plant with C-PPase with the objective of obtaining a transgenic beet plant having an increased sucrose content in the beet, or a reduced rate of sucrose breakdown during storage.

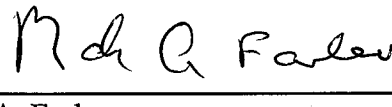
Moreover, even if one skilled in this art were led toward the use of C-PPase as a transgene in a sugar beet plant, he would still not be led by the disclosure of the cited references toward combining the use of such a C-PPase with a V-PPase since no hint is provided by the reference(s) that a V-PPase would increase sucrose content in the beet or reduce the rate of sucrose breakdown during storage. It is only the inventors of the presently claimed inventors who have surprisingly discovered that also a V-PPase can be used for the purpose of the present invention and, even more so, that a combination of C-PPase and V-PPase results in a synergistic effect which is entirely unexpected in light of the teachings contained in the cited art. In fact, none of the cited prior art mentions at all the possibility of obtaining a plant with a reduced rate of sucrose breakdown during storage, and in particular, of achieving this desirable effect by overexpressing a V-PPase together with a C-PPase.

For the reasons as set forth above, therefore, applicants respectfully request that the Examiner reconsider and withdraw the 'obviousness' of the present claims under 35 U.S.C. §103.

Respectfully submitted,

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